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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,938	07/22/2002	Srinivas Kaveri	TJK/209	8718
26689	7590	05/20/2004	EXAMINER	
WILDMAN, HARROLD, ALLEN & DIXON 225 WEST WACKER DRIVE CHICAGO, IL 60606			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/031,938

Applicant(s)

KAVERI ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 86-154 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 86-154 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 86-110 and 151-154, drawn to a method of determining the presence of anti-Factor VIII allo-antibodies and an anti-factor VIII allo-antibody.

Group II, claim 111, drawn to particular amino acid sequence.

Group III, claim 112, drawn to particular amino acid sequence.

Group IV, claim 113, drawn to particular amino acid sequence.

Group V, claims 114, 117-121, drawn to an analog of a particular amino acid sequence capable of inhibiting any site in the Factor VII molecule susceptible to lysis by an antibody and a method of neutralizing the antibody.

Group VI, claims 115, 117-120, 122, drawn to drawn to an analog of a particular amino acid sequence capable of inhibiting any site in the Factor VII molecule susceptible to lysis by an antibody and a method of neutralizing the antibody.

Group VII, claims 116, 117-120, 123, drawn to drawn to an analog of a particular amino acid sequence capable of inhibiting any site in the Factor VII molecule susceptible to lysis by an antibody and a method of neutralizing the antibody.

Group VIII, claims 124-129, drawn to a pharmaceutical composition comprising an anti-Factor VIII allo-antibody and a method of treatment using the composition.

Group IX, claims 130-135, 138-141, 144-148, drawn to a pharmaceutical composition comprising an inhibitor of Factor VIII allo-antibody, a method of using the inhibitor comprising a particular peptide or non-peptide analog listed in claims 135, 141 and 148 and an anti-factor VIII allo-antibody-catalyzed inhibitor.

Group X, claims 130-134, 136, 138-140, 142, 144-147 and 149, drawn to a pharmaceutical composition comprising an inhibitor of Factor VIII allo-antibody, a method of using the inhibitor comprising a particular peptide or non-peptide analog listed in claims 136, 142 and 149 and an anti-factor VIII allo-antibody-catalyzed inhibitor.

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Group XI claims 130-134, 137-140, 143-147 and 150, drawn to a pharmaceutical composition comprising an inhibitor of Factor VIII allo-antibody, a method of using the inhibitor comprising a particular peptide or non-peptide analog listed in claims 137, 143 and 150 and an anti-factor VIII allo-antibody-catalyzed inhibitor.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is drawn to a method of determining the presence of allo-antibodies while groups (V-VII) and (IX-XI) are drawn to analogs and inhibitors, respectively.

Groups II-IV are not related to any of the other claims.

Groups V-VII and IX-XI do not share unity of invention because the amino acid sequences of each groups are structurally different. Groups (V-VII) and (IX-XI) do not share unity of invention because they are drawn to different compounds.

Claims V-VII are drawn to analogs while IX-XI are drawn to inhibitors.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
May 19, 2004